UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

JONATHAN A. BLOOM,

Plaintiff,

v. Civil No. 5:16-cv-121

THOMAS E. PRICE, M.D.
Secretary of the U.S. Department of Health
and Social Services,

Defendant.

DR. BLOOM'S REPLY IN SUPPORT OF PLAINTIFF'S MOTION TO REVERSE/ OPPOSITION TO DEFENDANT'S MOTION TO AFFIRM

In August 2016, the Secretary conceded that "aside from the [Medicare Appeal Council's ("MAC")] reliance on the Medtronic website, the administrative record does not contain substantive evidence regarding why a [continuous glucose monitor ("CGM")] system is considered precautionary and/or is otherwise outside of the Medicare benefit category for [durable medical equipment ("DME")]." See Doc. No. 9 at 2. In light of that concession, and Dr. Bloom's showing that his CGM otherwise qualifies as DME for coverage, all that should remain is for the Court to determine whether the Medtronic website itself provides substantial evidence for the Secretary's decision that the Medtronic CGM is not "primarily a medical device" or is "non-medical" or whether the Secretary's denial is arbitrary and capricious. Because the Secretary attempts to apply the non-statutory/non-regulatory standard of "a primary medical device," the Secretary never actually attempts to make the proper showing. In any event, the Medtronic website certainly does not provide substantial evidence to support the Secretary's denial and the decision should be reversed.

I. The Court Should Issue an Order Reversing the Secretary's Decision.

A. The Secretary's Decision Is Not Supported by Substantial Evidence.

As provided in the regulations, a device is DME (and therefore eligible for coverage) if it meets a multi-part test, including that the device "is primarily and customarily used to serve a medical purpose." See 42 CFR § 414.202. In the appeals that are the subject of this case, the MAC denied coverage only on the basis that a CGM does not meet that element. Record2 at 27; Record1 at 10; Record3 at 11.[1] Although the Secretary previously conceded that (aside from the Medtronic website), there is not substantial evidence to support that conclusion, the Secretary appears to have changed his mind and now offers that there is substantial evidence to support the conclusion. Doc. No. 25 at 21-25.

On its face, the idea that a CGM is not "primarily a medical device" or is "non-medical" is difficult to follow. Record2 at 27; Record1 at 10; Record3 at 11. A CGM cannot make waffles, wash a car, or do WestLaw searches. In Dr. Bloom's opening papers, he showed that a host of authorities (including the Federal Drug Administration "FDA") consider a CGM to be primarily a medical device and that the Secretary failed to consider any of these in making a contrary determination. Doc. No. 34 at 4, 14, 15; Record3 at 460-466, 471-528, 644-725, 732-801 (studies); Record3 at 455-459, 467-470, 535-596, 624-643, 726-728 (consensus statement); Record3 529-534 (independent government technology assessments); Record3 at 208 (commercial payer coverage of CGM as a medical device); Doc. No. 10 at 2 (summarizing FDA approval). Dr. Bloom's showing in this regard is unrebutted.

[1] The Secretary produced three administrative records. The administrative record associated with the Secretary's Feb. 24, 2016 decision shall be cited as Record1; the administrative record associated with the Secretary's November 13, 2015 decision shall be cited as Record2; and the administrative record associated with the January 27, 2017 decision shall be cited as Record3. For the reader's ease, although documents may exist in all three administrative records, generally citation is made primarily to Record3 without redundant citation to Record1 and Record2.

Rather than the "primarily and customarily used to serve a medical purpose" test provided in the regulation, the Secretary seeks to recast the test as "used to serve a *primary* medical purpose." Record2 at 27; Record1 at 10; Record3 at 11. (emphasis added). That is a dramatic change from what is provided by the statute, regulation and National Coverage Determination ("NCD") 280.1. Although the statute, regulation and NCD 280.1 focus on whether the device is typically used for a medical purpose or for some other purpose, the Secretary's effort to recast the test focuses on the relative importance of the medical use.[2] In his Response to Dr. Bloom's opening papers, the Secretary continues to advance this new test, which is directly contrary to the statute, regulations and NCDs. Thus, on this ground alone, the Secretary's decision should be reversed.

Nothing in the statute or 42 CFR § 414.202 indicates that only one device can be "primarily and customarily used to serve a medical purpose" to manage a condition and is, therefore, DME. Indeed, it is to be expected that many conditions will require more than one piece of DME or intervention to manage. Doc. No. 34 at 16-18. Thus, the Secretary's effort to limit Dr. Bloom's DME coverage only to finger sticks is non-sensical and has no basis in the statute. Thus, all the Secretary's arguments that the Medtronic CGM cannot replace finger sticks simply miss the point. Record1 at 11; Record2 at 27; Record3 at 11. The issue is not whether a CGM eliminates the need for finger sticks. The issue is whether a Medtronic CGM (and related supplies) is "primarily and customarily used to serve a medical purpose" and there is not substantial evidence to conclude otherwise.

Because a CGM is DME within the meaning of the statute and regulations, the Court need not determine whether a CGM is a "blood glucose monitor" within the meaning of 42

[2] The relative importance of the medical use of the device is already captured in the "medically reasonable and necessary" requirement and simply has nothing to do with whether a device is DME. Here, that a CGM is medically reasonable and necessary for Dr. Bloom is unchallenged.

U.S.C. § 1395x(n), NCD 280.1, or LCD 27231. If the Court chooses to address that matter, there is not substantial evidence supporting the claim that a CGM is not a "blood glucose monitor." As the Court has previously noted, a CGM measures glucose in the interstitial fluid. Doc. No. 20 at 3. Glucose values in the interstitial fluid are correlated with glucose values in blood itself and are, therefore, an indirect measure of blood glucose. *See, e.g.*, Record3 at 473 (explaining that a CGM computes the glucose level by averaging the readings over a 5 minute period); s*ee also* http://www.medtronic.com/downloadablefiles/Diabetes%20Therapy%20-%20CGMS%20Fact%20Sheet.pdf (accessed 9/26/2017) (Page 2, "How do glucose levels in blood correspond to glucose levels in interstitial fluid."). Nothing in 42 U.S.C. § 1395x(n), NCD 280.1, or LCD 27231 limits the definition of "blood glucose monitors" to "direct blood glucose monitors" and there is not substantial evidence to support the conclusion that a CGM does not indirectly measure blood glucose and is, therefore, a "blood glucose monitor" and DME.

Further, even applying the Secretary's non-statutory, non-regulatory standard of "primary medical purpose," the CGM would satisfy Medicare coverage criteria. As noted in Dr. Bloom's opening papers, no other medical device provides glucose trend information or is capable of detecting the rapid and large glucose swings Dr. Bloom experiences. The Secretary does not suggest Dr. Bloom would be able manage his diabetes without a CGM. Indeed, because the finger stick method was insufficient to manage Dr. Bloom's diabetes, Dr. Bloom was prescribed a CGM.

Along these same lines, Health and Human Services' ("HHS") Civil Remedies Division has also held that the assertion that a CGM is "precautionary" is invalid under the reasonableness

standard. See Record3 at 270.[3] Thus, even applying the non-statutory "precautionary" test, HHS itself has concluded that it is simply unreasonable to contend that a CGM is "precautionary."

There is not substantial evidence to support the Secretary's conclusion that a CGM is not DME and the Secretary's decision should be reversed.

B. The Secretary's Decision Is Arbitrary and Capricious.

The Secretary did not address the fact that, without explanation, Dr. Bloom has received month-to-month inconsistent decisions regarding his own CGM and whether it qualifies as DME. Likewise, other Medicare beneficiaries have experienced the same inconsistent rulings.[4] Brief at 20. *See, e.g., Independent Petroleum Ass'n of Am. v. Babbit*, 92 F.3d 1246, 1260 (D.C. Cir. 1996) ("That is the very meaning of the arbitrary and capricious standard.").

Using his newly created test that only equipment that serves a "primary medical purpose" is DME, the Secretary relied on the non-statutory term "precautionary" to deny coverage. In his opening papers, Dr. Bloom showed that the Secretary's new test was arbitrary and capricious. In particular, the Secretary's claim that "[w]here an enrollee must still use another device to accomplish the medical purpose at issue, the device is essentially used as an additional precaution, but not for a primary medical purpose"[5] could not be squared with numerous other devices already determined to be DME. For example, the Secretary covers pacemaker *monitors* as DME and those would not fit the Secretary's newly created, non-statutory condition. Motion, Doc. No. 34 at 17. The Secretary's coverage of such adjunctive devices and presumptive laboratory tests demonstrates that the Secretary recognizes such devices serve a primary medical

[3] Although subsequently the HHS' Civil Remedies Division Ruling was vacated on procedural grounds that the Article could not be challenged through the LCD process, the analysis in the Ruling, which considered the peer-reviewed literature and consensus of experts, underscores that no evidence supported the proposition that a CGM is precautionary.

[4] *See, e.g.*, Record3 at 320 - 452 (Administrative Law Judge ("ALJ") decisions finding a CGM meets the definition of DME and is covered by Medicare). Although beyond the scope of this Court's review, more than 50 ALJ decisions have issued finding CGM is DME and covered by Medicare.

[5] *See* Record2 at 27; Record1 at 10; Record3 at 11.

purpose.[6] Accordingly, even taken on its own terms, the Secretary's decision, relying on the new test, is arbitrary and capricious. The Secretary's responsive papers before this Court are silent in this regard and Dr. Bloom's showing is unrebutted.

Accordingly, again, the Secretary has failed to respond to Dr. Bloom's showing that the Secretary's decision is not the result of difference in point of view or the product of agency expertise because the Secretary has failed to explain the contrary conclusion (except by simply re-casting the statute, regulations, and the NCD). *See Motor Vehicle Manufacturers Ass'n of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 63 (1983). Thus, Dr. Bloom's showing that the Secretary's conclusion in the present cases is arbitrary and capricious is unrebutted and the Secretary's decision should be reversed.

In a footnote, the Secretary contends that the arbitrary and capricious standard does not apply to its statutory/regulatory conclusion of not DME. Doc. No. 35 at 14, n. 14. This is so, the Secretary contends, because 42 U.S.C. § 405(g) limits review to "substantial evidence." That is simply incorrect. In relevant part, § 405(g) provides: "The findings of the Commissioner of Social Security *as to any fact*, if supported by substantial evidence, shall be conclusive[.]" (emphasis added). Thus, only factual conclusions are limited to the "substantial evidence" standard by § 405(g). Legal conclusions/opinions may be reviewed using any of the standards applicable for review under the APA, including the arbitrary and capricious standard. The finding that a CGM is not DME is not a factual conclusion, instead it is a legal conclusion/opinion comparing the facts to the Secretary's proffered reading of the statute. As

[6] Medicare covers a hospital bed as DME when "the patient's condition requires positioning of the body; e.g., to alleviate pain, to prevent contractures, avoid respiratory infections, in ways not feasible in an ordinary bed." NCD 280.1 and 280.7. A hospital bed does not treat the underlying condition and does not direct a therapy – it is used to prevent the exacerbation of the condition and consequences therefrom. The fact that other devices might be used to treat the condition does not deprive a hospital bed of a medical purpose.

detailed above, that legal conclusion/opinion is arbitrary and capricious and the Secretary has not rebutted Dr. Bloom's showing otherwise.

II. Response to Defendant's Motion for an Order Affirming.

The Secretary's arguments that a CGM is not DME and that the Secretary's decision should be affirmed are addressed above. The only new argument presented in the Secretary's Motion to Affirm is the charge that this Court lacks subject matter jurisdiction to consider some of the claims in this case. There is no merit to that argument.

A. The Court Has Subject Matter Jurisdiction Over All the Claims.

On appeal are three matters arising from the same case or controversy (i.e., the Secretary's refusal to cover Dr. Bloom's CGM and related supplies): M-15-1505 (CGM sensors); M-15-15-4332 (CGM transmitter and sensors); and M-16-10554 (CGM sensors).

With respect to M-15-4332, the Secretary does not even suggest a lack of jurisdiction. With respect to that matter, it is undisputed that, by itself, that matter exceeds the amount-in-controversy (AIC) requirement of 42 U.S.C. § 1395ff(b)(1)(E), and otherwise is ripe for review. Accordingly, the Court has subject matter jurisdiction over, at least, M-15-4332 and should reach the merits of that claim.

With respect to M-15-1505 and M-16-10554, the Secretary suggests a lack of jurisdiction on the ground that those matters, considered individually, do not meet the AIC requirements of 42 U.S.C. § 1395ff(b)(1)(E). Doc. No. 35 at 15-16.

That argument is based on a simple misreading of the Medicare statute, the Federal Rules of Civil Procedure and/or a failure to consider 28 U.S.C. § 1367 (supplemental jurisdiction). This Court has subject matter jurisdiction over M-15-1505 and M-16-10554 applying either the Medicare statute directly or exercising this Court's supplemental jurisdiction.

1. This Court Has Jurisdiction Under 42 U.S.C. § 1395ff(b)(1)(E).

For appeals of adverse decisions under Medicare, Congress established a detailed scheme. The scheme makes a distinction between appeals at the departmental level and those at the judicial level, with different requirements for each.

At the departmental level, the statute provides, in part: "(i) In general – A hearing (by the Secretary) shall not be available under this section if the amount in controversy is less than $100 …" Subsection (ii) addresses aggregation of claims *by the Secretary* and allows aggregation of claims by a single individual (I) or among multiple individuals (II). "In determining the amount in controversy, the Secretary, … shall allow …" Subsection (ii) does not address aggregation of claims at the judicial level. Clearly, the Secretary has no power to aggregate matters in front of the Court, as that is a power of Congress and/or the Court.

At the judicial level, the statute provides that "… judicial review shall not be available *to the individual* if the amount in controversy is less than $1,000." 42 U.S.C. § 1395ff(b)(1)(E)(i) (emphasis added).[7]

Pursuant to FED.R.CIV.P. 18, "A party asserting a claim, counterclaim, crossclaim, or third-party claim may join, as independent or alternative claims, as many claims as it has against an opposing party." In assessing whether a Complaint by a single plaintiff against a single defendant meets AIC requirements, all the claims are aggregated. *See, e.g., Snyder v. Harris*, 394 U.S. 332, 335 (1969) ("Aggregation has been permitted … in cases where a single plaintiff seeks to aggregate two or more of his own claims against a single defendant[.]"). Consistent with this conclusion is the fact that § 1395ff(b)(1)(E) confers jurisdiction based on the "individual" not meeting the AIC rather than a "claim." *Compare Wolde-Meskel v. Vocational-*

[7] Subsection (iii) alters the dollar amounts using an inflation adjustment mechanism based on the Consumer Price Index (CPI) starting in 2004.

Instruction Project Community Services, Inc., 166 F.3d 59, 62 (2nd Cir. 1999) (noting that diversity statute is based on "civil actions" rather than "claims" and aggregating claims to meet AIC requirement); *see also Pavano v. Shalala*, 95 F.3d 147, 150 (2nd Cir. 1996) ("Denial of relief by the Appeals Council is a final decision of the Secretary, which may be appealed to the district court (if the aggregate amount in controversy is $1,000 or more).").

Applying the above to the present case, it is clear that this Court has subject matter jurisdiction to consider all the claims. Using the figures supplied by the Secretary, the amounts associated with each claim are: M-15-4332 ($1,976); M-15-1505 ($473); and M-16-10554 ($1,419). Together, the claims total: $3,868. For 2016, when this case was originally filed, the CPI adjusted AIC required by § 1395ff(b)(1)(E) for judicial review was $1,500. 80 FR 57827, 57828 (Sept. 25, 2015). Thus, the AIC requirement was met by M-15-4332 (by itself) or by the combination of any or all of the claims.

Accordingly, simply applying the Medicare statute and the Federal Rules of Civil Procedure, this Court has subject matter jurisdiction to consider all the claims.

2. This Court Has Jurisdiction Under 28 U.S.C. § 1367(a).

Title 28, Section 1367(a) provides:

> Except as provided in subsections (b) and (c) or as expressly provided otherwise by Federal statute, in any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution. Such supplemental jurisdiction shall include claims that involve the joinder or intervention of additional parties.

This is generally referred to as "supplemental jurisdiction." Under the statute, as long as the Court has original jurisdiction over one matter, the Court may exercise jurisdiction over other matters that form part of the same case or controversy. This is so, even though the Court would lack jurisdiction over the other matters if considered separately. Supplemental jurisdiction is not

limited to cases arising under state law or in matters where jurisdiction is based on diversity. *See, e.g., Pierre v. Plant Automotive, Inc.*, 193 F.Supp.3d 157, 170-73 (E.D. N.Y 2016).

Applying the above, this Court has jurisdiction to consider M-15-1505 and M-16-10554. First, it is not contested that the Court has jurisdiction to consider M-15-4332. Accordingly, this Court has original jurisdiction. Second, it does not appear to be disputed that M-15-1505 and M-16-10554 form part of the same case or controversy. M-15-1505 and M-16-10554 arise from a common nucleus of operative fact with M-15-4332 (i.e., all the appeals are for sensors or a transmitter for a CGM system for Dr. Bloom). Finally, supplemental jurisdiction is not precluded by § 1395ff(b)(1)(E)'s AIC requirement. That requirement does not expressly contradict § 1367(a), the statutes are not irreconcilable, and (given jurisdiction over M-15-4332), exercising supplemental jurisdiction will not inundate the courts with trivial claims. *See, e.g., Pierre v. Plant Automotive, Inc.*, 193 F.Supp.3d 157, 170-73 (E.D. N.Y 2016) (similar analysis applied to the MMWA).

Accordingly, if necessary, this Court may exercise supplemental jurisdiction over M-15-1505 and M-16-10554 in light of original jurisdiction to consider M-15-4332.

3. The Secretary's Arguments Lack Merit.

Pages 15-18 of the Secretary's brief are dedicated to the Secretary's lack of jurisdiction argument. In the Secretary's view, the fact that a process of aggregation is provided at the departmental level, somehow rewrites the statute's provisions regarding judicial review (changing "to the individual" to "on each claim"), by implication repeals FED.R.CIV.P. 18 for Medicare cases, and also, by implication, repeals the supplemental jurisdiction statute for Medicare cases. None of the cases cited by the Secretary supports these propositions.

Of course, interpretation of a statute starts with the words of the statute itself. *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 409 (1993). Remarkably, the Secretary's brief never

addresses the actual words of the statute at issue. In relevant part, § 1395ff(b)(1)(E)(i) provides: "… judicial review shall not be available to the individual if the amount in controversy is less than $1,000." Thus, as noted above, the statute confers/limits jurisdiction based on the *individual*, not on the claim. Nothing in the statute, regulations, or case law indicates, much less dictates, otherwise.[8]

All of the Secretary's arguments regarding aggregation at the department simply miss the point that "judicial review" is based on an individual (not a claim) meeting the AIC requirement. The Secretary is silent on this point and also does not address FED.R.CIV.P. 18 or supplemental jurisdiction.

With respect to the cases cited by the Secretary, none of them stands for the proposition that judicial review requires that each *claim/cause of action* meet the AIC separately. Thus, for example, the Secretary cites *Schwartz v. Medicare*, 832 F.Supp 782, 790 (D. N.J. 1993). There, the total AIC was $850 and the plaintiff had not exhausted his administrative remedies. Likewise, in *Baruch v. Schmiegelow*, 175 Fed.App'x 422 (2nd Cir. 2006), the AIC was $250.

The Secretary cites *Epstein v. Burwell*, 2014 WL 12591476 (C.D. Cal. 2014) when stating: "As the Medicare rules direct, aggregation cannot occur at the judicial review stage." Response at 17. *Epstein* seems to have no bearing on the present case. In *Epstein*, the named plaintiff had an AIC of $147. Nevertheless, Epstein filed suit in District Court contending that: 1) he was the representative of a class of absent members that, aggregated, met the AIC requirement; and/or 2) his own future claims could be aggregated to meet the AIC requirement.

[8] Indeed, the same analysis applies to appeals before the Secretary. In relevant part, § 1395ff(b)(1)(E)(i) provides: "A hearing (by the Secretary) shall not be available *to an individual* under this subsection if the amount in controversy is less than $100[.]" (emphasis added). What the provisions of § 1395ff(b)(1)(E)(ii) address is aggregation of *claims* to the individual seeking to appeal. See 42 U.S.C. § 1395ff(b)(1)(E)(ii) ("Aggregation of claims –"). Thus, under the statute, an *individual* has to have an AIC of at least $100 to get a hearing. That figure can be arrived at either independently or by aggregating claims to the *individual* (see § 1395ff(b)(1)(E)(ii)(I)) or even among *individuals* (see § 1395ff(b)(1)(E)(ii)(II)).

Thus, simply as a factual matter, *Epstein* is far afield from the present case where a single plaintiff with multiple claims (at least one which meets the AIC requirement by itself) seeks judicial review.

Dr. Bloom takes no position of whether *Epstein*'s discussion of aggregation of a class at the judicial review level is correct (especially when the named representative does not meet the AIC). As noted by the District Court there, there are many considerations regarding exhaustion of administrative remedies, identity of claims, and even standing to represent unidentified class members. *Id*. at 4. In its decision, the District Court did not discuss FED.R.CIV.P. 8, or 23, or supplemental jurisdiction[9] and it is unclear how, if at all, those considerations would have affected the Court's conclusion or how the Court would address a case brought by a single plaintiff. In short, *Epstein* seems to be entirely inapposite.

During proceedings below, Dr. Bloom twice sought extensions of time to file a District Court action on M-15-1505, stating that the appeal in that matter and what became M-15-4332 "need to be consolidated in order to meet the federal amount in controversy requirement." *See* Record2, M-15-1505 at 3, 8. Dr. Bloom sought only an extension of time to file a District Court action and did not seek to aggregate claims before the department. The Secretary suggests that Dr. Bloom's request for an extension was recognition of a "flaw" in not aggregating claims before the Secretary. Doc. No. 35 at 16-17. Nothing could be further from the truth. Indeed, the opposite is true and Dr. Bloom's requests for an extension fully track both the statute and proceedings in this case.

[9] In *Epstein*, the court quoted *Heckler v. Ringer*, 466 U.S. 602 (1984) as stating that 42 U.S.C. § 405(g) is the "sole avenue for judicial review of all claims arising under the Medicare Act." While that was true when stated, in 1990, Congress enacted 28 U.S.C. § 1367 (supplemental jurisdiction) which substantially broadened federal jurisdiction in cases where the court has original jurisdiction over at least one claim.

Under Medicare regulations, a party seeking judicial review must file an action in District Court within 60 days of a Council decision (or obtain an extension). *See* 42 CFR § 405.1130; 42 CFR § 422.612. Further, there is no guarantee that appeals before the Council will be decided in the order they were originally filed or at any specific time. Thus, depending on the order in which multiple appeals are decided and the timing thereof, it is possible for jurisdiction to be defeated in a District Court on the matters individually for failure to meet the AIC requirement even though, if considered together, those same appeals would meet the requirement. For example, in the present case, M-15-1505 (where the amount in dispute is $473) issued on November 13, 2015. More than 60 days later, M-15-4332 (where the amount in dispute is $1,976) issued on February 24, 2016. Absent an extension to file in the District Court or aggregation before the department with another claim, judicial review of M-15-1505 would be precluded because it fails to meet the AIC individually.

In recognition of the above, Dr. Bloom sought an extension of time to file his District Court action so that M-15-1505 and M-15-4332 could be litigated at the same time and meet the amount for judicial review. His request was granted. Record2 at 1. As noted, M-15-4332 meets the AIC by itself and provides a basis to consider M-15-1505 either directly under the statute or as a result of supplemental jurisdiction. Accordingly, with an extension, there was simply no need for Dr. Bloom to aggregate claims before the department.

As detailed above, this Court has subject matter jurisdiction.

III. Conclusion.

For the foregoing reasons, Dr. Bloom respectfully requests that the Court grant his Motion for Order Reversing Secretary's Decisions and deny the Secretary's Motion for Order Affirming Decisions.

Dated at Burlington, Vermont this 26th day of September, 2017.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Craig S. Nolan, counsel for Jonathan A. Bloom, do hereby certify that on September 26, 2017, I electronically filed with the Clerk of Court the following document:

DR. BLOOM'S REPLY IN SUPPORT OF PLAINTIFF'S MOTION TO REVERSE/ OPPOSITION TO DEFENDANT'S MOTION TO AFFIRM

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Dated at Burlington, Vermont this 26th day of September, 2017.

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